Co-Funded by the Horizon 2020 programme of the European Union

Grant Agreement: 875358

Deliverable D3.1

Hospital Cloud-Network Infrastructures Integration Methodology

Work package:	WP3 – Hospital Infrastructures, Visualisation & Distributed Ledger Technology (DLT)
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Status:	Final
Date:	30/03/2021
Version:	1.0
Classification:	Public

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30/03/2021

Authorised Date:

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FAITH Project Profile

Contract No H2020-ICT- 875358

Acronym	**FAITH**
Title	**a Federated Artificial Intelligence solution for moniToring mental Health status after cancer treatment**
URL	**https://www.h2020-faith.eu/**
Twitter	**https://twitter.com/H2020_Faith**
LinkedIn	**https://www.linkedin.com/company/faith-project/**
Facebook	**https://www.facebook.com/H2020.FAITH**
Start Date	**01/01/2020**
Duration	**36 months**

FAITH Partners

List of participants

Participant No	Participant organisation name	Short Name	Country
1 (Coordinator)	WATERFORD INSTITUTE OF TECHNOLOGY.	WIT	Ireland
2	UPMC Whitfield, Euro Care Healthcare Limited.	UPMC	Ireland
3	Universidad Politécnica de Madrid.	UPM	Spain
4	Servicio Madrileño de Salud.	SERMAS	Spain
5	UNINOVA, Instituto de Desenvolvimento de Novas Tecnologias.	UNINOVA	Portugal
6	Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud.	CF	Portugal
7	Deep Blue.	DBL	Italy
8	Suite5 Data Intelligence Solutions Limited.	SUITE5	Cyprus
9	TFC Research and Innovation Limited.	TFC	Ireland

SC1-DTH-01-2019: Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

H2020-SC1-DTH-2019

FAITH is co-funded by the European Commission - Agreement Number 875358 (H2020 Programme)

Document Control

This deliverable is the responsibility of the Work Package Leader. It is subject to internal review and formal authorisation procedures in line with ISO 9001 international quality management system procedures.

Version	Date	Author(s)	Change Details
0.1	2/11/2020	Fernando Ferreira (UNINOVA)	Table of Contents
0.2	3/12/2020	Fernando Ferreira (UNINOVA)	First draft version.
0.3	14/01/2021	Ricardo Matias / Pedro Ferreira (CF)	Contribution to the CF sections and general contributions.
0.4	20/01/2021	Maria Eugénia Beltran (UPM)	Contribution to the SERMAS sections and general contributions.
0.5	23/02/2021	Michael Feterolf, Kate Connors (UPMC)	Contribution to the UPMC sections and general contributions.
0.6	25/02/2021	Fernando Ferreira (UNINOVA)	Consolidated version.
0.7	25/02/20221	Philip O'Brian (TSSG)	Internal review.
0.8	26/02/2021	Fernando Ferreira (UNINOVA)	Revised draft version.
0.9	23/03/2021	Tom Flynn (TFC)	QA'd version.
0.9.1	25/03/2021	Tom Flynn (TFC)	QA'd version - second review.
1.0	30/03/2021	Gary McManus (WIT)	Final release for submission to European Commission portal.

Executive Summary

Objectives:

Deliverable D3.1 will present the architecture and protocols to establish the relationship between FAITH and the existing hospital cloud/network infrastructure and to provide the interface capabilities that extends and complements the hospitals by means of the interaction with the FAITH platform and services. Objectively, the task undertaking (T3.1), is aimed at defining the pathways of interaction between the services on both sides, the paths for the flows of data and the actors involved and the assigned responsibilities that, ultimately, will impact in the security, performance and safety of the overall infrastructure and data. The descriptions shaped in the FAITH Project Protocol will enable the arrangement of the data sets that will, selectively in a validated manner, become part of the FAITH execution results to the Hospital project participants, and in response to the required information. The data flow is dynamic and will improve the knowledge capacity for the doctors and their decision making. Data will be collected, generated, protected and analysed so that IoT and analytics data made available from within the FAITH ecosystem will be fed into the hospital infrastructure and requests from the medical specialists and technical staff will flow in the opposite direction to the FAITH infrastructure. The provision of such operations from the technical and human point of view will support and promote the best interaction for the success of the trial's implementation and development, projecting for further exploitations and execution in the future.

Results:

The output of task T3.1 will increase the levels of detail provided for the interactions between the FAITH project framework and the participating hospitals. This document will support the execution of the trials by clarifying how this relationship is made, in operational terms and a definition of how the data from the FAITH ecosystem can be seamlessly integrated to provide a singular view of all data required by the professionals. The final users may request for different data granularity or modification of the frequency of data retrieval, thus embodying their feedback to the FAITH platform and possible new requests.

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1 ABBREVIATIONS AND ACRONYMS

Abbreviation	Description
AI	Artificial Intelligence.
D	Deliverable.
DLT	Distributed Ledger Technologies.
EC	European Commission.
Edge computing	Processing of data occurs at the source of data. When data is physically located closer to the users who connect to it, information can be shared quickly, securely, and without latency.
FL	Federated Learning.
GDPR	General Data Protection Regulation.
ICT	Information and Communication Technologies.
IoT	Internet of Things.
ISO	International Organization for Standardization.
KPI	Key Performance Indicator.
WP	Work Package.
SSL	Secure Socket Shell.
WP2	Stakeholders identification, uses cases definition, requirements specification and architecture design.
WP3	Hospital Infrastructures, Visualisation & Distributed Ledger Technology (DLT).
WP4	Big Data Analysis & Federated AI Services.
WP5	Modular, extendible Data capture App.
WP6	Integration, Trials & Validation.

2 INTRODUCTION

This deliverable, D3.1, is aimed at defining the relationship between FAITH developments and technological deployments and the existing hospitals' infrastructures.

The research being developed by the FAITH Project research team is aimed at providing insights on the patient's mental state, where patients belong to a specific population of individuals that underwent cancer therapy sessions. Mental health, being an intrinsic condition of the individual, can be assessed both by asking the subject and performing measurements that can lead to an insight about possible mental states for that individual. FAITH is bi-directional; interacting with the individuals and making the necessary questions and interpretations and collecting relevant data. In this case, nutrition, sleep, activity and outlook are the parameters to be used as indicators of the individuals' present mental state. The framework will collect data, analyse it and produce insights of relevance for the clinicians. This process implies several stages to be considered; data must be collected using the most unobtrusive methods, to minimize impact in patients in an already potentially fragile condition, such data will become a source for producing relevant insights while ensuring the standards of privacy for citizen personal information and the security of the collected data and resulting insights. Finally, such data must become available to clinicians so that it will empower them for the best clinical decision leading to a better timely assessment of a patient's mental health.

These are some of the challenges embraced by FAITH research that will collect data, analyse and produce insights over all patient's collected data while ensuring security, data integrity and patient's data privacy along the whole process. This working model will have the objective to establish a framework that, using the most accurate methods and security procedures will produce indicators of a patient's mental health that will be provided to the medical doctor and can take the form of a warning, so that the doctor can be supported on a possible decision about calling the patient and providing him the best care.

The undertaking encompasses two major phases, which is outlined as follows: The *first phase* during the project execution where the major goal is the establishment of boundaries and defining key markers of declining mental health conditions. At this stage, researchers will find the best means to collect data from sensors, questionnaires and IoT devices, store and prepare it for the data analysis process aiming to find the best analytics to generate biomarkers of mental health decline. Such that will be presented to the medical doctors that follows and provides care for that patient's mental health. This will be done securely and respecting the patient's privacy by data anonymization and safe communications and storage of information. The *second phase*, consists in, once the methodology is defined and there is an understanding of what variables should be collected and what analytics should be applied, deploy a

framework able to collect data from a patient. From the analysis of such data, it will be possible to generate biomarkers that will trigger alerts to clinicians once an identified risky situation is detected for a given patient. This deliverable aims at presenting the methodology for establishing this flow of information that ultimately, aims at providing to the clinicians, on time, the relevant information about a patient, in the selected condition of having had cancer treatments, providing that if that person presents with mental health decline then it is necessary to make clinicians aware so that support can be properly delivered, aiming to prevent further decline and promoting the recovery and improvement of that person's mental health status. The evaluation of the mental health condition of a patient has then to be carried by mental health professionals from the cancer treatment institution or those who provide counselling for the patient in any circumstance along his life. In the scope of research and development of technological tools, as in the present case of FAITH research project, it is necessary to use standardized procedures that are applied to all patients in a trial. With that requirement in mind, it is necessary to understand how to establish a relationship between FAITH and the hospitals and how the data from the patients can be obtained with all the ethical procedures and safety for patients' data. In this case, it is possible to envisage a multitude of considerations about data gathering and how such data is handled. Concerns include; the existing patient's data that is safeguarded at the hospital, data gathered during the scope of the project that refers to the hospital's patients, the relationship between the hospital and the patient engaging the trial and the relationship between the hospital and the project.

Hospitals are complex infrastructures that include many types of assets that should be available and appropriate to the setting and to support the health care professionals to serve the target population (WHO, 2018). The hospital itself has the professionals in different areas that ensure the patient relationship and the data management in the different domains that include diagnoses, treatment and follow up. Data is collected manually and by devices. The data in the hospital has several degrees of complexity that involve internal security, the integrity of data, the relationship between patient and doctor, the storage and processing of information and the rules of access to such data. All this framework is dependent on the ethical protection from the individual hospital ethical board and above, the national law that can delegate part of the ethical concerns to the hospital's ethical board, nevertheless, ensuring that data protection is protected by that board's rules. From this description, the complexity and limitations for the execution of trials is evident. It arises from legislation and entities' specific regulations (Theofanidis and Fountouki, 2019).

In order to design a clinical trial and make it possible for all the procedures to be executed in a timely manner, it is necessary to address each concern and ensure compliance with all requirements. In order to achieve such endeavour, some strategies can be followed concomitantly by implementing strict measures and avoid the most intrusive procedures, in terms of reducing the burden of the trial in the relationship

with the hospital. This means, the less need for resources, human or digital, and the less need or data leads to lessen the likelihood of being rejected by the ethical board, diminishing the procedures and time to wait for approval and thus, increasing the probability of success. In addition to such obstacles, it is important to notice that, in the case of the imperious need to interface of the hospital, technological developers would need to know the characteristics and specificities of each hospitals, their systems and the information flow. But, since hospitals are complex structures with multiple systems and configurations, sometimes modular and self-evolving according to specific needs and technology availability, it is important to understand that, not even the hospitals have broad all-cases strict rules about the security. Their systems are many times ensured by third parties, meaning that equipment and data flows and respective security rules are locally specific and imply the restriction of the interactions from the outside to the hospital, in all those above mentioned aspects, with the understandable premise that knowledge about those systems will increase their vulnerability. All measures are important and all safety precautions should be taken as there are reports of past healthcare data breaches, some involving the exposure of hundreds of thousands of records (Davis, 2020). Adding to these facts, common to other technological systems, the hospitals are ruled by ethical boards, data protection officers and security advisors that have the mission to restrict the interactions and risks of exposing the hospital infrastructure to external threats. That becomes a legitimate barrier for interactions between the hospital and the exterior, where new interactions are scrutinized, and exposure must be kept to the strictly essential operations. FAITH interactions aim at empowering the clinicians in their capacity of decision, meaning that the hospital infrastructure is not a need for the interaction and that the flow of information is possible without physical protocols or service dependencies between FAITH and the clinicians. To promote safety, security and efficiency, humans are therefore the main link for these interactions.

Hospital procedures are based on several mechanisms that, once methodically applied, ensure the functional requisites for the information systems infrastructure but also the requirements of privacy for personal data and its security and data protection. That is also a ‘must have’ for the FAITH platform and services, which is shaped in the requirements specification on WP2 and in all technical work packages such as WP3, WP4, WP5 and WP6 but also ensured in the FAITH/Hospital connection to ensure there is no flaw in the FAITH project execution. That is also a primary objective of the presented document, to define and make clear how FAITH interlinks with the hospital infrastructure taking into account the human link as the key element and fundamental insurance of all operations.

FAITH project context

The organization of the project trials is crucial for the success of the FAITH project. In this sense, there are several complementary works that, together, characterize the project trials in its different dimensions. That is the case of WP2 requirements and interfaces' description, WP3 interface and visualization for the doctors and technical personnel and WP5 with the app interfacing and collecting data from the patients. WP4 establishes the FAITH federated framework and analytics while WP6 performs the Integration, Trials and Testing that, ultimately develops the Trials and completes the cycle with validation and KPI measurements.

Figure 1 - FAITH Technical Work Packages

The execution of the trials occurs in three distinct locations, Ireland, Portugal and Spain, involving respectfully the UPMC Whitfield, Euro Care Healthcare Limited Hospital, the Hospital in The Champalimaud Foundation for the Unknown and Hospital General Universitário Gregorio Marañón.

Trials execution will begin after the recruitment process that will occur in each hospital. Prior to that stage is the approval by the ethical boards of each hospital, a mandatory requirement before any trial involving patients, both because of legislation demands and internal hospital regulations. The clinicians will observe the characteristics of their patients, evaluating their profile and their adequacy to the trial in several dimensions including their pathologies, autonomy (e.g., patients in hospital are not in the scope of the project) and the technical concerns including devices and smartphones to be used. In general, the trials aim to disturb patients as little as possible and to become harmonized with the general practices of the

hospital and the clinical staff. In technical terms, this is achieved by the mediation of humans thus achieving the absence of any physical connection between FAITH infrastructure and the hospital infrastructure. In fact, an external link to the hospital would threaten data integrity and security of the network and cloud infrastructure, which would be a complex process as there are third parties involved in the infrastructure and there is contractual liability between the parties. In that sense, due to the characteristics of the FAITH platform, it is an unnecessary requirement to gather data from the hospital since clinicians inside the hospital may acquire such data as normally happens in routine clinical practice. Below, Figure 1 summarizes the whole interaction between patients and hospitals mediated by the FAITH Central platform established for the three trials.

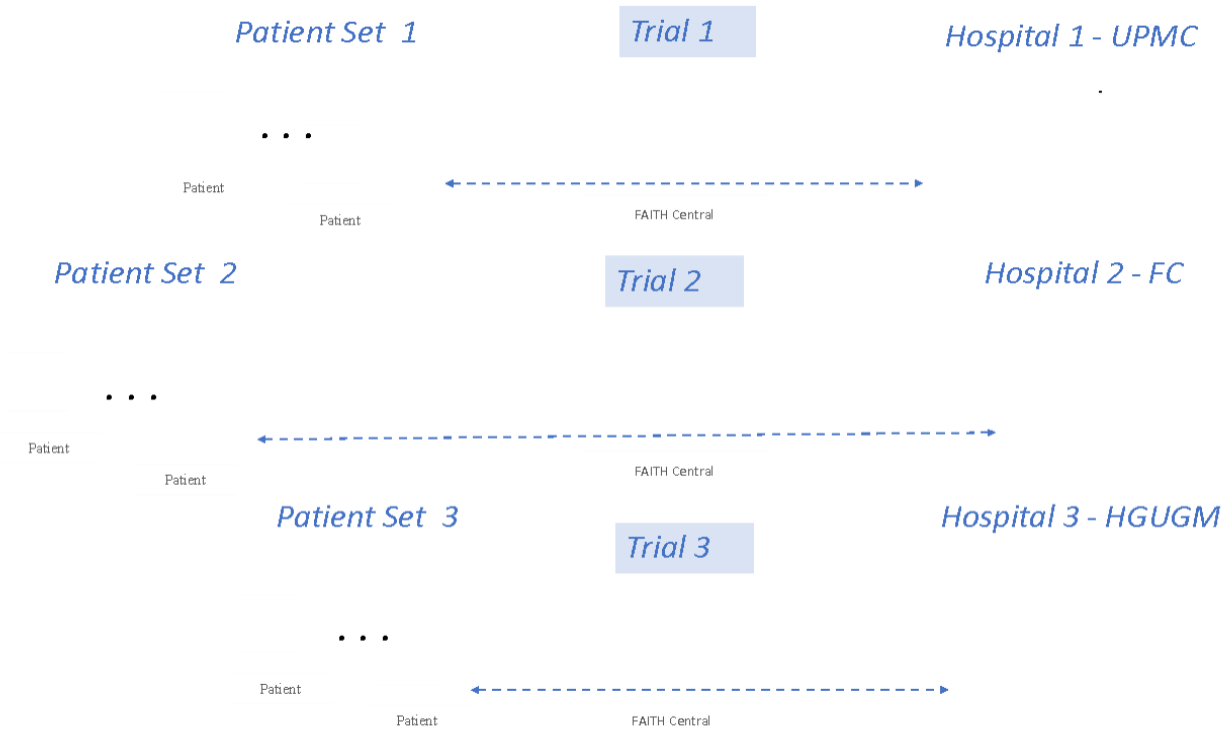

Figure 2 - The Trials are managed by Faith by Technologically linking patients and Hospitals

Privacy, Security and Data integrity

The connection between a research project and patients, instantiated in an outsider host institution, is a matter of concern since data and results need to be observed, validated and results presented to the clinical team, regarding all the necessary procedures to ensure safety and protection of data. If research occurs inside the hospital, and thus using the hospital infrastructure, the risks are considerably lessened.

In the case of an outside research activity, the concerns arise from data capture to data handling and later in the communication from exterior services and the integration of applications into the hospital infrastructure. If such integration becomes possible, it must comply with a number of certifications and address all the concerns of the hospital infrastructure administrators, which can be a long hard path and subject to a possible rejection from the ethical board and data protection officers. The most important concern for hospital ethics and, by consequence, to IT administrators is to ensure data safety and security so that privacy of a person's data is never at risk. It is important to notice that privacy is not a strict need for patients, it is also important for doctors to preserve their notes and observations and their digital activity. To ensure privacy it is a good practice and, in most of the cases mandatory, that the hospital retreats from allowing external access to their networks. That practice is even more enforced while in temporary experiments and when there are no other options available. Furthermore, it is known that any modification to the existing practices and operating protocols or modifications in the existing infrastructure must be scrutinized by the IT administrators. If there is any relevant change, submit a proposal to the Data Protection Officer that will analyse the risks, confront the researchers with the necessary questions, propose different solutions and, in line with those remarks, prepare the documentation to submit a well characterized modification to the Ethical Board In synthesis, the larger the network's exposure to the exterior the larger becomes the risk for the network and data. All those considerations bring to the point that it is highly recommendable to avoid all kinds of interference with the hospital infrastructure, keep it apart and promote safety.

The link is a person

The hospital services should be the most secure defenders and enforcers of the best practices in data management supporting procedures that apply the most secure and trustable technological approaches. Much investment and accurate planning ensures the integrity of the hospital network, with the infrastructure including many resources for the gathering, processing and storage of data from equipment and clinical personnel. This includes the multiplicity of hospital devices in widespread locations where data is acquired from multiple sources; data that would become useless if not accessed by personnel (e.g. clinicians, nurses) in different locations of the hospital. It means that in order to keep such a system secure, but at the same time functional in allowing professionals' access to clinical data, it is important to have strict rules, enforced by the Ethical Board and data protection officers. But all the best practices and regulations would be useless if the hospital infrastructure was exposed to external threats as those posed to companies, government and even individuals with cyber-attacks that pose serious threats including the now most popular ransomware attacks. In these attacks, the vulnerabilities of the infrastructure are explored and used for attacks that steal data or encrypt data so it becomes useless unless a payment is

made to the attackers. Having this in mind, it is not wise to promote practices that open the hospital networks to the exterior, exposing to new vulnerabilities as new communication channels are established. These considerations are at most importance especially while considering that hospitals need to be trustful institutions for patients, clinicians and the society, where a citizen must feel secure in delivering personal information and being monitored by trustful people and secure systems. In that sense, the FAITH project establishes a set of data management best practices that ensure safety and integrity for collected data. The analysis of a patient's data as previously determined will generate reports and alarms that will feed the deployed services to clinicians and involved hospital staff thus, avoiding any direct interaction with the hospital digital infrastructure. This is an insurance that no risk is posed to the hospital network and that there will be no disturbance or added effort to the existing management infrastructure keeping it all secure and trustable without any added vulnerability or the need to open for the project's execution of trials.

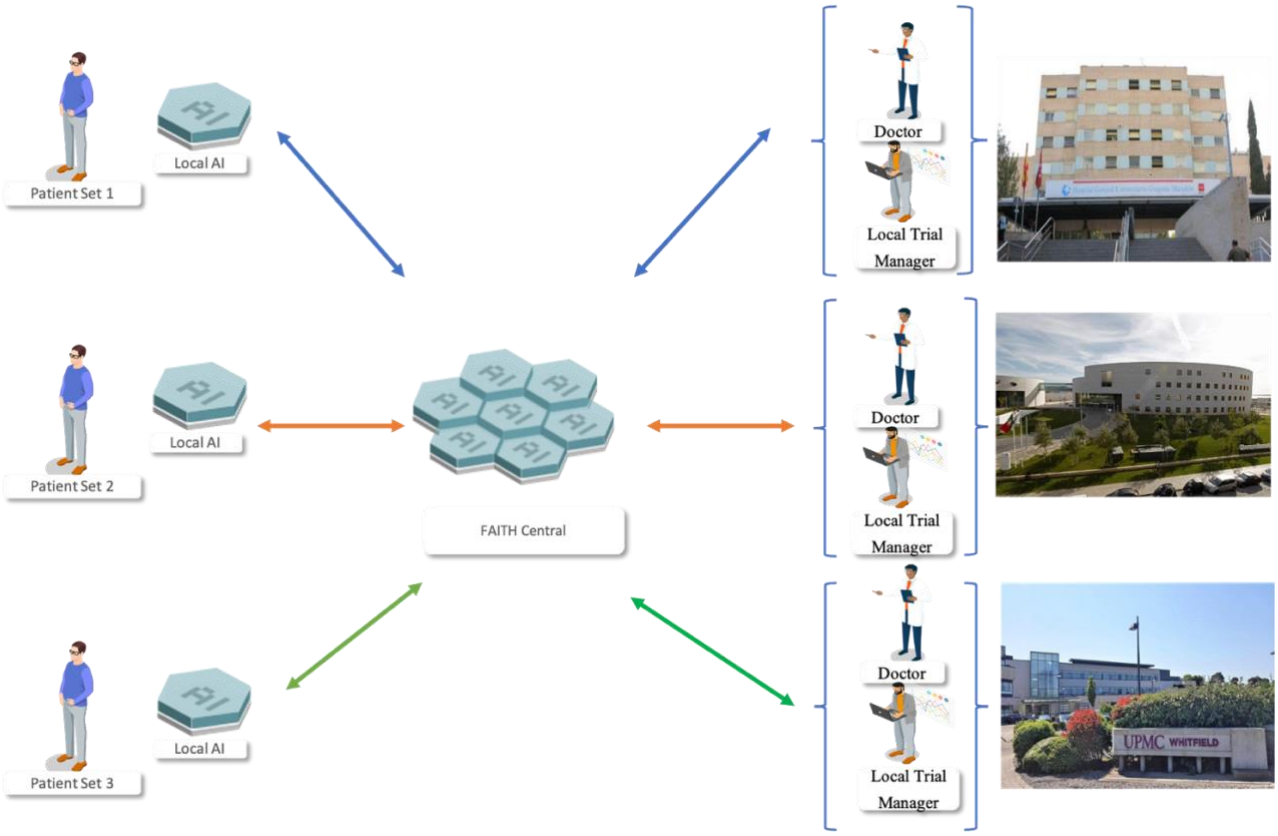

Figure 3 - Overview of FAITH Trials an explanation of trust

In this sense, we can talk about a “human API” as the humans play the role of interface between the FAITH platform and the hospital, enforcing the security of data and supporting all kind of ethical concerns that could arise, by avoiding any digital connection with the hospital infrastructure.

Security and Standardization

FAITH Framework will comply with General Data Protection Regulations (GDPR) and will follow standard procedures to ensure data privacy and security. Data privacy and protection deliverable, resulting from Task 3.3, will present the security and privacy to be enforced in all developments of the FAITH framework. In that sense, data protection is highlighted in the compliance with GDPR and the security of the communications with ISO 27001:2013, annex A13.2 using Secure Socket Shell (SSH), with randomized ports to minimize the risks of known port attacks. The framework will be protected by firewalls and defence to the known threats to this kind of networks. Beyond the external threats, confidence will be reinforced by the use of Distributed Ledger Technologies (DLT) in the registry of all access logs in the Blockchain so that they will be preserved and auditable. The FAITH Framework aims at providing the best security standards, known so far thus ensuring the trust of patients participating in the Trials, and the confidence of the hospital’s Ethical Boards. Software development should follow ISO/IEC 25040 Software product Quality Requirements and Evaluation (SQuaRE) in order to ensure high standards of quality for the FAITH software components. The FAITH consortium will use applicable standards, where possible so that the development meets requirements and that the products and services meet high standards allowing sustainable development so that evaluation and auditing ensures the desired levels of validation.

3 HOSPITALS

Hospitals are a major infrastructure of the healthcare systems. They comprise the most diverse types of systems and highly skilled personnel in a wide variety of areas, in health and beyond. To keep a hospital running, medical doctors are the first association that comes to mind, but there is much more in a myriad of specialization areas that cover all the needs for patients and professionals. Hospitals are, in technical terms, a large and organized assembly of instruments and devices in a variety of equipment types and connections. All those technological assets address the needs for monitoring devices and medical instrumentation, for the most different purposes and, an almost invisible infrastructure that captures and stores data, making it available where needed and connecting almost everything everywhere, inside the hospital facilities and beyond.

Networks and interfacing devices in the hospital infrastructure have requirements that must be designed, implemented strictly observed in the whole information lifecycle in a hospital infrastructure. They aim to ensure security, privacy and protection of data while ensuring that systems are accessible and open to only those entitled to such information or allowed to make use of those information repositories. The diversity of devices and multitude of personnel in the hospital imposes strict rules to accomplish such goals while ensuring the proper operation and support to clinical systems and medical teams in the hospital.

The above-mentioned requirements are needed to the hospital infrastructure and must be ensured in all its dimensions. However, if those are important at the hospital level, it means that the same level of security, confidentiality and data protection must be followed before information reaches the inside infrastructure of the hospital from an outside source. That is where concerns reach the FAITH infrastructure.

The main goal of the FAITH project platform and services is to ensure the same levels of security and privacy, as in the hospitals, is to ensure the same type of requirements that will be followed and enforced in the project infrastructure of data and services. This is to say that there is a flow between the project and the hospital even if in between there is the human link. In electronic analogy, a capacitor is not an obstacle to the current flowing in an AC circuit, this same analogy depicts what is to be the linkage between FAITH and the hospitals.

The contribution of the three partner hospitals and the number of participants in each trial are a valuable source of information to be collected, in an Edge computing approach, allowing the federated learning (FL) to generate more valuable results from the ensemble analysis of all anonymised information.

3.1 Hospital General Universitario Gregorio Marañón

Figure 4 - Hospital General Universitario Gregorio Marañón

HGUGM is a public hospital that belongs to the Madrid Health Service, which stands out for the high training and qualification of its professionals, for its teaching and research capacity and for its technological endowment, being a national and international reference in various specialties.

This hospital has a lot of expertise in clinical trials and data collection for clinical variables and has the optimal structure to assess and validate the FAITH project involving real end-users (both clinicians and patients). Also it has the logistical support of the Foundation for Biomedical Research of Hospital Gregorio Marañón (FIBHGM for its acronym in Spanish) to review and manage the test contract in compliance with the regulations.

Medical Oncology Infrastructure

The Medical Oncology Service of the HGUGM is integrated by a multidisciplinary team of professionals, which provides comprehensive and individualized care to the patient in the different oncological pathologies. The unit is a national and international reference in assistance, teaching and research in the area of cancer, and continues to introduce innovations to improve day by day the quality of diagnosis,

treatment and caring for patients. Also, it is certified in Quality by AENOR, according to ISO 9001: 2008 since November 2015.

This Service has the following human resources:

- Oncologists
- Nurses
- Nursing assistant
- Coordinator of the Research Unit
- Clinical trial and Translational Studies Coordinator
- Data entry.
- Administrative Staff
- Other health professionals (Medical and Non-medical services)

It also has the following facilities:

- Healthcare facilities
  - Day Care hospital
  - Hospitalization area
  - Medical room & nursing consulting
  - Oncology pharmacy department
  - Case management
- Oncology Quality departments
- Research facilities
  - Research unit
  - Early phase Unit
  - Translational Oncology Lab
  - Research team
  - Documentation file room.
- Bioinformatics unit

Ethical concerns

The research ethics committee protects the rights of potential participants, it must also take into account potential risks and benefits for the community in research and promoting high ethical standards in health research.

3.2 Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud

Figure 5 - Fundação Champalimaud

The Champalimaud Foundation (CF) is a private, non-profit organisation dedicated to research excellence in biomedical science. Completed in 2010, the Champalimaud Centre for the Unknown (CCU) is a state-of-the-art centre for basic and translational research, and for the diagnosis and treatment of diseases, from neurological disorders to cancer. Housing the Champalimaud Clinical Centre (CCC), its multidisciplinary teams focus their activities on the patient, offering care of excellence based on the most advanced technological means, with a focus on clinical research and practice in cancer, systems pathology and neuropsychiatry.

The neuropsychiatry unit (NPU), from which several members of FAITH within CF are part of, is composed of physicians and other clinical professionals, as well as researchers who are devoted to deepen the knowledge on neuropsychiatric disorders, and ensures a high degree of precision in diagnosis, as well as a rigorous definition of treatment according to standard international guidelines. Aside from providing care for patients at the CCC, the NPU also works closely with research. The lung unit, from which patients will be recruited to participate in FAITH, works daily to improve the burden of lung cancer. All members of the Unit are experts in the diagnosis and treatment of diseases of the lung, and particular relevance is placed on risk assessment and early diagnosis as being central to prevention of cancer and the efforts to control its progress.

An overview of the CCC hospital infrastructure presents an hospital that is interlinked with the research part of the institution, where it is prominent the profile of the researcher/doctor. Basically, the patient

management is a proprietary system from Glintt that handles all the processes of admitting patients, scheduling consultations, verifying presences and data from the consultations itself. Regarding the support for non-textual information, it comprises images and data from specific examination procedures. It includes Anatomical Pathology using Anapat Glintt, Clinical Pathology using Apollo Synlab, Nuclear Medicine exams using PACS Caretream and finally Surgical procedures by Olympus.

Each system has its own and independent database. All the systems have redundancies and snapshots are taken on a daily basis but also weekly, monthly and annually taken snapshots ensure the integrity of the databases. Adding to this, all the databases are hosted remotely, and all databases are kept in two different physical places. The operating network is closed in itself and to have access it is necessary to have a VPN to access each specific network. This contextualization is aimed to provide clues on

Ethical Concerns

The Champalimaud Foundation Ethical Committee is responsible for supervising all the patient related procedures, either in the regulation of the activities that require patient engagement and in all patient data protection aspects. The Data Protection Officer will provide advisory to the Ethical Committee and will establish the technical requirements for the implementation of the Trial in all aspects of the engagement of the CF in FAITH Trials. In this regard, informed consent and data protection are at the foundations of any of such Trial developments, but also the accurate support and communication to patients, providing information of their rights, namely the right to opt out at any point of the Trial execution. Data protection becomes an aspect to be insured in all data acquisition, management and communication.

3.3 UPMC Whitfield, Euro Care Healthcare Limited

Figure 6 - UPMC Whitfield, Euro Care Healthcare Limited

UPMC Whitfield Hospital, an 80-bed hospital is the largest private hospital in the South East of Ireland and offers patients the right care, in the right way, at the right time – in a first-class facility that is close to home. Established in 2006, UPMC Whitfield Hospital provides diagnostic imaging, physiotherapy, medical and radiation oncology and elective surgery to both public and private patients. "UPMC's mission is to serve our community by providing outstanding patient care and to shape tomorrow's health system through clinical and technological innovation, research and education."

Owned by University of Pittsburgh Medical Centre (UPMC), a non-profit organisation that is a recognised leader both in providing healthcare services in the United States and sharing that knowledge to build outstanding healthcare services with parties around the globe. UPMC has renowned centres of excellence in transplantation, cancer, neurology, sports medicine, geriatrics and women's health.

Our oncology services are part of the UPMC network of cancer centres in the United States, these world leaders in cancer services assist in the delivery of the most advanced treatment and care possible to patients in the South East of Ireland.

UPMC Whitfield has achieved a number of quality certifications and accreditations (JCI, CHKS, ISO 9001, ISO 50001, ISO 18404). By achieving and maintaining quality standards, we adhere to the highest standards of patient safety at all times. UPMC Whitfield collaborates closely with the public health system hospitals in the Southeast Region Waterford University Hospital is the largest public hospital in the region with 550 beds hosting regional speciality services.

Ethical Concerns from UPMC:

UPMC Trial managers will be concerned to implement measures that will prevent a Patient Health Information (PHI) data breach, meaning that it is of most importance to ensure that a patient's (passive or actively input) information is not breached and his or her status as a patient of UPMC will not be disclosed to unwanted parties as a result. Also to concern if the decision on the introduction of a patients' healthcare records to be populated into the patient's health record. In that case a patient could request for his or her health records (Subject Access Request) to be included in their records as the study is administered by UPMC as a pilot site.

UPMC is also concerned in clearly inform the patients about Opting out, meaning to ensure the patient's understanding as to how someone can remove themselves from the study and clear patient understanding of what is meant by "passive data capture" i.e., measurement of data not directly input by the patient (movement, etc.) and how one can opt out from that process.

The last concern from UPMC relates to the misinterpretation of health or patient reported data. This implies a clear explanation to the patient (in the consent form or application) the association (or speculated association) between the metrics and one's health status (depression, etc.) i.e. patient should be reviewed by a healthcare professional, patient health outcomes presented on the app do not necessarily imply illness.

The hospital has legal responsibilities as a Data Controller in relation to the information which is kept on computer or in a structured manual file about individuals. It is important that steps are taken to protect the privacy of each individual and ensure that sensitive personal information is handled legally, securely, efficiently and effectively in order to deliver the best possible care. Once full information is available on how the hospital and FAITH will interact/exchange data we will complete a Privacy Impact Assessment to identify potential risks around the collection and use of personal health information - this is conducted in the initial stages of a project in order to protect the rights of patients. Individual specific patient consent will be required in relation to the pathway of data for each patient participating in the study. If there is sharing of personal health information across systems a data processing agreement will be required for

all systems. This must contain details of server management and location and data architecture and flow (diagram) and data destruction policy, etc.

4 INTERACTIONS BETWEEN FAITH AND THE HOSPITALS

The FAITH project is a joint endeavor of partners from different domains, research, business and Healthcare Institutions and with a diverse skills base. The partners collaborate in the scope of the project under the Information and Communication Technologies (ICT) H2020 framework programme, but have different views of the health domain, different approaches roles and interventions. The Research partners have an opportunity to apply technology and scientific knowledge to the health domain in concrete Trials, using previous knowledge and background tools and systems to new opportunities to develop, deploy and increase knowledge. Hospitals have also the will to increase knowledge but above that, the opportunity to provide better care and to promote the quality of services provided to their patients, to find new pathways and new solutions to known healthcare problems and to use new technology to empower clinicians to provide the best treatment and care for patients. Business partners have the skill to develop new solutions to healthcare clients, to establish new opportunities to collaborate with the hospitals, to widen their capacity in the market and in overall to make possible that technology become part of sustainable business models that can promote their services in the healthcare domain while strengthening the links to research partners, their source of evolution and cooperative development. This is a collaborative ecosystem where all, have much to win in different dimensions and patients will be the overall beneficiaries of all the project developments and new promoted solutions. In order to make this collaboration work and become fruitful for the project's commitments and contractual obligations, it is necessary to clarify what are the roles and what are the competences and interlocutors in the different stages of the project with an especial focus to the Trials. The whole project is well defined in the Description of Work and all participants know what to do at what timing, mediated by work package leaders and the Project Coordinator. The special concern happens to be related to the interactions with patients and the harmonization between the project and the healthcare institutions. Those have the regular work plus the additional load from the project either in terms of personnel as to the relationship with patients with one different kind of the interaction, the recruitment and engagement in the Trials. That is what makes that stage of the project different, the one-year Trial execution that demands clear rules, smooth execution and an established information of who is responsible for the interventions in each institution. This is the reason for the present section where the Trials become personalized with associated names for the Trials to be developed in each of the three participant Hospitals. It is therefore of major importance to know that, when each Trial starts and develops its activities there are assigned persons to become the interlocutors of the project in the institutions with a resulting safety and reliability both for the project and the participant institutions. In the next sections, it is explained who those persons

are as they will be the human interfaces and will promote the smoothest linkage between FAITH and the Healthcare institutions.

4.1 Information in a Faith Trial, local information and Faith Acquired

Information is the element of interaction between the FAITH platform and the hospitals. For that reason, data and information generated by the algorithms will be defined in terms of its origin and destination.

The patient, as the central element of the project, will be the source of information and the central focus for the whole project. Information will be acquired from the person in three main modalities: from sensors and devices such as accelerometers, microphones, sleep trackers belonging to the smartphone, IoT devices or wearables (e.g., wrist bands, smartwatches). The second modality will be the interaction of the patient with the smartphone via questionnaires, selecting options, etc. The third modality is by human-to-human interaction such as personal consultations at the hospital or phone interviews in line with the teleconsultation. The information gathered from the devices will analysed using AI best strategies where algorithms will be used to extract biomarkers, envisaging the adoption of an Edge computing approach, with data being analysed at the patient's device, being then sent to the platform. The questionnaires and tactile information provided by the smartphone will be analysed and sent to the FAITH platform. In any case, such information will be encrypted and sent in a secure channel to the platform, thus ensuring data security and patient privacy. The information provided in the human-to-human modalities will be processed and sent to the platform with the same regards of security and privacy. Finally, the analysis performed by the FAITH platform will be managed and characterized by doctors and researchers in what regards to its relevance and integration in the pool of parameters to be considered.

Distributed Ledger Technology

The technologies using distributed ledger (DLT) are these days a safeguard of secure, non-delectable and non-editable information. In the healthcare domain, this is some kind of paradox since there is the GDPR rules and the right to be forgotten to be promoted in the healthcare domain. The fact is that, information is only protected if not exposed to unauthorized personal, and or that, it is necessary to audit and to be able to track and trace who have had access to patients' clinical records. In this case, where different actors will operate, configure and develop the systems, it is important to map and to have trustable records of data access. This is where DLT becomes used, as a mean to securely store the logging information and to have a clear registry of who accessed each piece of data. DLT is more known for cryptocurrency and then for smart contracts but should also be considered as a powerful support for indestructible record. In the case of FAITH those will be the records about access to data.

4.2 Dataflows to be part of the Hospital - FAITH interactions

In order to tackle those organizational challenges, a cyclic methodology is developed to gather requirements, propose a functional representation of FAITH – Hospital enrolment, validate the proposed approach and reframe according to the feedback until a consensual approach is reached.

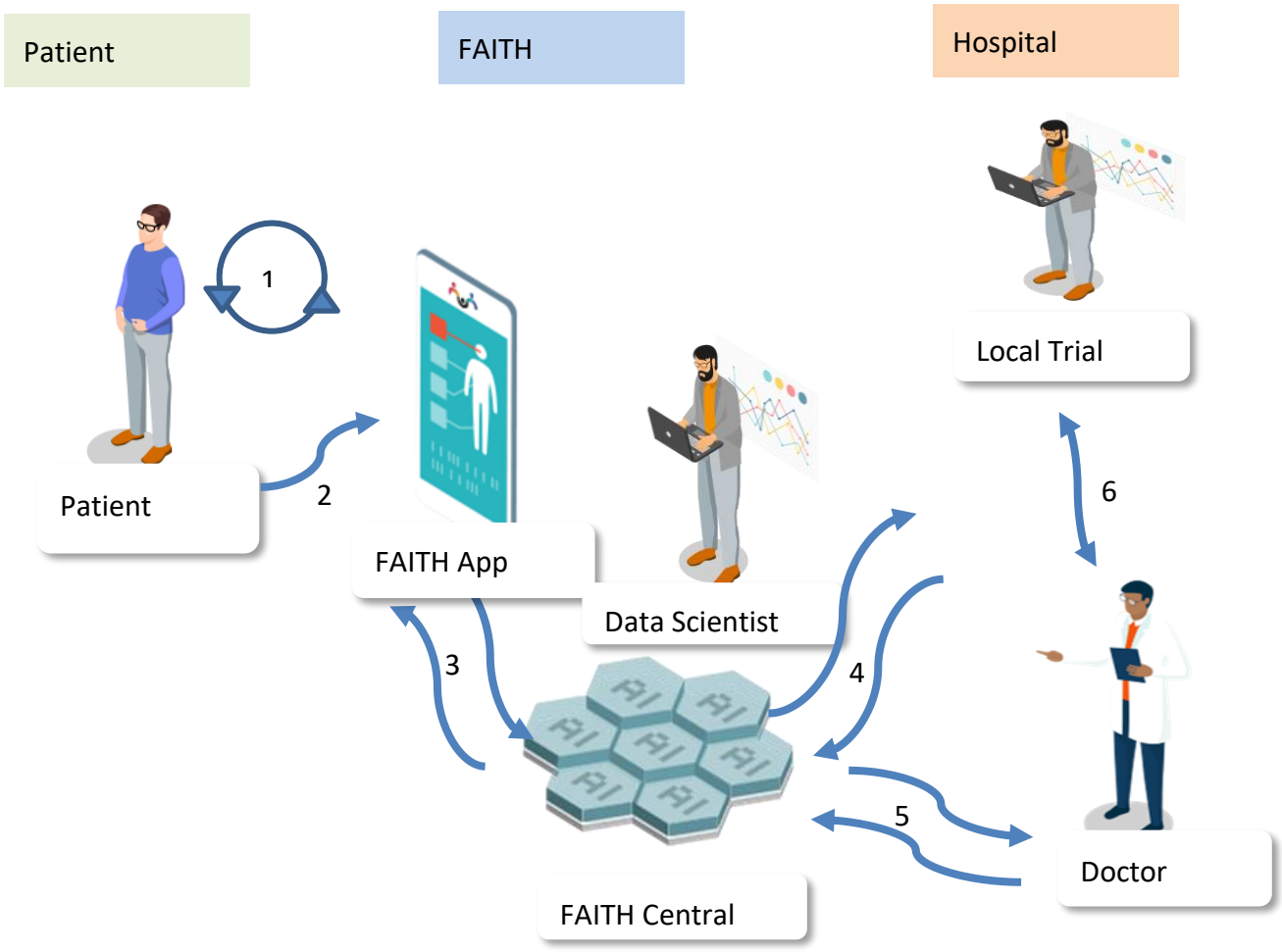

Figure 7 - FAITH Scenario, interactions and flows of information

Information Flows

- There is a cyclic flow of audio information between the application and the patient
- There is a flow of digital information from the patient to the Application (sensors, detectors, etc)
- Information flows between the application and the FAITH Platform whereas the Data Scientist analyses it
- Information flows from the Platform to the local trial coordinator?

- Nevertheless, the doctors in the trial may want to consult data, any time, regarding their patients
- Periodical reports are sent to the doctors in the trial and the doctor may ask for report adjustment

4.3 Levels of Interaction in a FAITH Ecosystem, Trial Instantiation

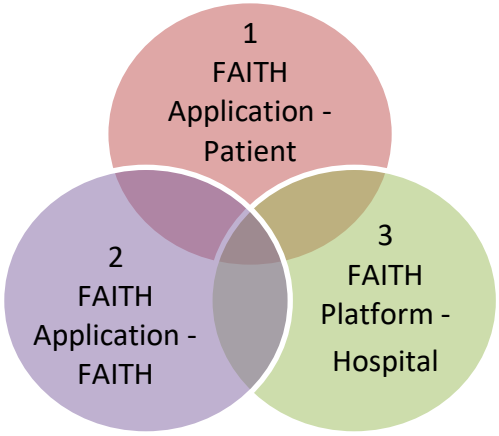

Figure 8 - According to the requirements 3 levels of interaction are established

The FAITH Application collects data from the patient.

The sensing ecosystem

The smartphone-based application uses sensors and sleep monitoring devices to retrieve data from the patient in an obtrusive manner as the process is silently running in the background. Data is analysed and biomarkers are revealed according to AI pre-processor assignments. The FAITH platform algorithms applied over existing data will, according to clinicians' instructions, provide the relevant indicators for a person's mental health assessment. Data is analysed with low power algorithms, due to the limitations of smartphones processing power that will produce the metrics for that patient that will be sent to the doctors.

The FAITH Application interacts with the FAITH platform

The Application has several modalities of interaction with the FAITH platform. In order to specify those modalities, it is important to understand the application model of operation so that it becomes clear what data will be collected analysed and which results should be sent over the network. In any case, questionnaires and sensor data are central to these operations. The application will collect sensor data from the smartphone sensors along with data from the bed sleep tracker or from a fitness band. These

are the hidden processes that do not require patient interaction. On the other hand, there are mental health questionnaires proposed to the patient which he will answer by voice or using displayed buttons.

The platform will send digest either from questionnaire scoring or algorithm appliance over the collected sensor and IoT data that is sent to the FAITH platform. The platform in turn will issue requests for new data modalities or other types of interaction that becomes relevant. This implies the other type of interaction where the hospital receives data and issues new protocols for data collection, stating what data will be needed in future interactions in order to uphold a diagnostic or propose new insights over that person's mental health condition.

The FAITH platform Interacts with the Hospital

Data collected and analysed by the FAITH platform, based on clinical guidance and algorithm application will generate reports to the hospital. Those reports, either textual or graphical, aim to make a capture of the patient's present health situation and the insights that are possible to generate with available data. Based on these reports, the clinicians will make use of their interface and visualization interface to reason according to the clinical data of the patient, available hospital data and data from the FAITH platform to decide and, eventually, issue new requests for data and biomarkers that will support their diagnostics or point to new assessment pathways.

4.3.1 Functionalities the FAITH App for the engagement of the patient

Questionnaires - The FAITH platform issues the most appropriate questionnaires to the App.

Sensor Data - The App generates reasoning over the sensor data and sends to the FAITH platform.

Food Intake - The App generates reasoning over data collected about Nutritional habits to the FAITH platform.

4.3.2 Functionalities the FAITH platform will provide to the Hospitals

RAW Data - The platform will provide Raw Data, whenever necessary, to the clinicians and data scientists.

Graphics and Tables – The platform will provide different possibilities to visualize data providing insights.

AI Biomarkers - The platform will identify relevant biomarkers either from App digest or algorithm intense processing

4.4 Modalities of Interaction in a FAITH Ecosystem

The importance of the engagement between FAITH, the patients and the hospital institutions will be analysed next. The primary goal refers to the interactions to be developed in the context of the trial execution but that will be useful for further engagement of patients in the FAITH resulting paradigm which also impacts in exploitation of FAITH results in the future.

4.4.1 Actors

FAITH Trials Coordinator - FTC

Local Trial Coordinator - LTC

Patient attending the Trial - PaT

Hospital Technical Expert - HTE

Oncologist participating in FAITH - OpF

Psychiatrist participating in FAITH – PpF

FAITH App - FApp

FAITH Platform - FP

4.4.2 Engagement stage

The engagement stage comprises the following steps:

Selection – The hospital takes the requirements from FAITH and selects potential participants. (LTC, OpF)

Interview – Patients are interviewed asking for participation. (LTC, PpF)

Register - The accepted patients are registered at the Hospital for the trial including demographic data (LTC).

Anonymization - A Trial number is issued by the LTC to the Patient becoming thus anonymous to the project. (LTC)

Engaging – The patient is briefed, and application is installed at the personal smartphone. (LTC, PaT)

Home appliance – When eligible a sleep device is installed and configured by a hospital technician. (PaT, HTE)

4.4.3 Starting the trial

The technical execution of the Trial comprises the following relational steps:

Initialization – Each hospital will issue a report with the requirements for each engaging patient. (LTC)

Setup – Interaction between the hospital and the project to solve any remaining issues. (FTC, LTC)

Readiness – notification of technical and clinical readiness from hospital and patients. (LTC)

Depart – The trial coordinator signals the start of the trial to FAITH researchers and hospitals. (FTC)

Collection of Sleep data – the application receives sleep data either from the under-mattress or fitness band. (FApp)

Collection of Activity data – sensors from the smartphone track activity with different granularity. (FApp)

Collection of Nutritional information – The app retrieves information about the patient's nutritional habits. (FApp)

Questionnaires – the App retrieves information in the form of Questionnaires (by language or text). (FApp)

Data processing - edge computing strategy allows the application of algorithms. (FApp)

4.4.4 Clinical evaluation and 6 monthly trial validation

During the project execution, a 6-month trial validation will be performed by each hospital regarding their trial execution, including results and patient engagement.

Clinical evaluation comprises the following relational steps:

Patient's attendance – patient participation, difficulties, success cases, points to improve. (LTC, OpF, PpF, HTE)

Activity Evaluation – analysis of the relevance of the Activity indicators. (LTC, OpF, PpF)

Nutritional Evaluation – analysis of the relevance of the Nutrition indicators. (LTC, OpF, PpF)

Sleep Evaluation – analysis of the relevance of the Sleep indicators. (LTC, OpF, PpF)

Outlook Evaluation – analysis of the relevance of the Outlook indicators. (LTC, OpF, PpF)

Feedback – After analyzing data and results, feedback will be sent to the FAITH platform. (LTC)

The feedback from each hospital will be sent to the FAITH technical coordinator that will develop the necessary efforts, with the FAITH researchers' team to promote the next evolution and Trial technical update to be sent to the Trial Coordinator.

4.4.5 Finalization of the Trials

At the end of the Trials' execution each hospital will proceed with the final data collection and analysis and report to the Faith Trial Coordinator. This will be the conclusion of the patients' engagement with the FAITH Trial.

Trial local conclusion – The local trial coordinator will meet with all hospital participants. (LTC, OpF, PpF, HTE)

Trial Report – The Local Trial Coordinator will report the results to the FAITH Trial Coordinator. (LTC)

5 ROLES AND ENTITLEMENT OF EACH TRIAL EXECUTION INTERACTIONS

The execution of the trials, beyond the technological setup, will be managed by persons. It is thus of most importance to clarify, before start, who will be responsible for the interfacing between participants. In that sense, this document, counting with the participation of the three hospitals and FAITH Description of Work, presents the persons in charge of each activity thus removing the barriers that could result from undefined assignments. It is now possible, to adjust with people in charge the regulation of the relationships between hospitals, people developing the Trial and the FAITH central. This step aims to promote the best success of the Trial execution promoting the best performance of FAITH Trials' execution.

FAITH Project Coordinator – Gary McManus (WIT)

FAITH Technical Coordinator – Philip O'Brien (WIT)

FAITH Trials Coordinator – Maria Eugénia Beltran (UPM)

5.1 Hospital General Universitario Gregorio Marañón

Persons that will be this Hospital Actors

Local Trial Coordinator - LTC: María del Monte

Oncologist participating in FAITH - OpF: Miguel Martín Jimenez (IP in HGUGM), Sara lópez-Tarruella

Nurses participating in FAITH – NpF: Tatiana Massarrah, Marta Cantero

5.2 Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud.

Persons that will be this Hospital Actors

Local Trial Coordinator – LTC – Raquel Lemos (Psychologist)

Hospital Technical Expert – THE – Ricardo Matias (Senior Researcher)

Oncologist participating in FAITH – Nuno Gil (MD, Oncologist)

Psychiatrist participating in FAITH – Albino Maia (MD, Psychiatrist)

5.3 UPMC Whitfield, Euro Care Healthcare Limited.

Persons that will be this Hospital Actors

1. Local Trial Coordinator – LTC – Kate Connors/ Katie Delahunty
2. Patient attending the Trial - PaT – Breast and Lung radiation oncology patients (to be confirmed in protocol)
3. Hospital Technical Expert – HTE - Operations Manager of UPMC Whitfield Cancer Centre
4. Oncologist participating in FAITH – Of – Dr. Esam Ab del Aal
5. Psychiatrist participating in FAITH – PpF – not relevant for Irish Pilot site

6 CONCLUSIONS

This deliverable presents the relationship between the FAITH project and the participating hospitals. It provides the background for the establishment of the FAITH trial organization in terms of the services and information flows, the people involved and the overall view of how the operationalization of the FAITH trials. As in any trial, it is important to define the role of each participant and the way those participants interact with each other. In particular, this is an important issue when individuals are involved and their privacy, security of data and its trustworthiness are the most important assets to be ensured. In that sense, this document plays a central role by providing the guidance for the development of the necessary pathways for the onset implementation of the trials' linkage between the different participants but also to support the continued operation of the trials during the project execution. It should also become a reference when presenting the project internally or fostering the engagement of stakeholders. This document is complemented by the protocol document in defining how the project operates and will be base for the best practices in a FAITH environment, especially in what regards to the trial's execution.

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